

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Arnold J. MANDELL, et al.

Serial Number: 10/777,829

Filing Date: February 11, 2004

Title: ALGORITHMIC DESIGN OF PEPTIDES
FOR BINDING AND/OR MODULATION
OF THE FUNCTIONS OF RECEPTORS
AND/OR OTHER PROTEINS

Group Art Unit: 1631

Examiner: John S. Brusca

CONFIRMATION NO: 5723

FILED ELECTRONICALLY ON: April 6, 2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be made of record in the above-identified application. Each item of information contained in this information disclosure statement was cited in communications from applications in the same family as the current application. The information provided herewith is not material to the patentability of the claimed invention, either because the information does not disclosed or render obvious the claimed invention, is not prior art, and/or is cumulative to references cited already by the applicants.

US publication No.s 2003/0176656 and 2005/0119454, and US Patent No. 6,560,542 have the same inventors and same priority date as the current application and, therefore, are not prior art. Likewise, the article by Mandell et al. is not prior art because it is by the same inventors as the current

application and it was published after the priority date of the application. The article by Grana, et al., is not prior art as it was published after the priority date of the current application.

Furthermore, the articles by Bangalore, et al., Manavalan, et al., and Doherty, et al., and US Patent Nos. 5,374,621 and 5,639,885 are not material to the patentability of the claimed invention because these references do not disclose or render obvious the claimed invention. Bangalore, et al., discloses antiserum raised against tyrosine phosphorylated forms of p185 and the related epidermal growth factor. Manavalan, et al., discloses studies of hydrophobic character of amino acids in globular proteins in order to predict secondary structure of such proteins. Doherty, et al., discloses mono-D-amino acid scan on the C-terminal of Endothelin hexapeptide antagonists. US Patent No. 5,374,621 discloses methods of retarding vascular leakage caused by tissue injury by administering neurotensin or a neurotensin analog. US Patent No. 5,639,885 discloses peptides containing dihydropyridine-pyridinium salt-type redox system which provides site-specific and sustained delivery of peptides to the brain. None of these references disclose the retro-inverso peptides of the claimed invention. Furthermore, none of the references teach or suggest the retro-inverso peptides of the claimed invention. Therefore, these references are not material to the patentability of the claimed invention.

Finally, US Patent Nos. 4,522,752 and 4,732,890 and the article by Taylor, et al., are not material to patentability of the claimed invention because these references do not disclose or render obvious the claimed invention and the information is cumulative to references cited already by the applicants. US Patent No. 4,522,752 discloses retro-inverso peptides and peptides derivatives in the form of analogues of bradykinin potentiating peptide (BPP_{3a}). US patent No. 4,732,890 discloses retro-inverso hexapeptides of neurotensin analogs. The article by Taylor, et al., discloses retro-inverso peptides of prosaptide. These references are cumulative because Applicants already cited a reference in the previous IDS that illustrated to the Examiner that retro-inverso peptides were known in the prior-art. None of the references disclose or teach the sequences claimed in the current application. Therefore, these references are not material to patentability of the claimed invention.

A. ☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
- ☐ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --

- ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(c) provided concurrently herewith;
- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(c);
- AND --
- ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ 37 CFR §1.97(e). Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);
- AND/OR --
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);
- AND/OR --
- ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E. ☐ Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.
- F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

- ☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

- ☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

- ☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

- ☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 31010-701.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 6, 2007

By: Albert P. Halluin
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/777,829	
			Filing Date	February 11, 2004	
			First Named Inventor	Arnold J. Mandell	
			Art Unit	1631	
			Examiner Name	John S. Brusca	
Sheet	1	Of	2	Attorney Docket Number	31010-701.301

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US 2003/0176656	09/18/2003	Mandell et al.	
	2.	US 2005/0119454	06/02/2005	Mandell et al.	
	3.	US 4,522,752	06/11/1985	Sisto et al.	
	4.	US 4,732,890	03/22/1988	Bonelli et al.	
	5.	US 5,374,621	12/20/1994	Wei	
	6.	US 5,639,885	06/17/1997	Bodor	
	7.	US 6,560,542	05/06/2003	Mandell et al.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 905.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST-3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST-16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and resubmitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/777,829	
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			Art Unit	1631	
			Examiner Name	John S. Brusca	
Sheet	2	Of	2	Attorney Docket Number	31010-701.301

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁴
	8.	BANGALORE, et al. Antiserum raised against a synthetic phosphotyrosine-containing peptide selectively recognizes p185new/erbB-2 and the epidermal growth factor receptor. <i>Proc Natl Acad Sci U S A.</i> 1992; 89(23):11637-41.		
	9.	DOHERTY, et al. Structure-activity relationships of C-terminal endothelin hexapeptide antagonists. <i>J Med Chem.</i> 1993; 36(18):2585-94.		
	10.	GRANA, et al. CASP6 assessment of contact prediction. <i>Proteins.</i> 2005;61 Suppl 7:214-24.		
	11.	MANAVALAN, et al. Hydrophobic character of amino acid residues in globular proteins. <i>Nature.</i> 1978; 275(5681):673-4.		
	12.	MANDELL, et al. Cellular and Behavioral Effects of D2 Dopamine Receptor Hydrophobic Eigenmode-Targeted Peptide Ligands. <i>Neuropsychopharmacology.</i> 2003; 28 Suppl 1:S98-107.		
	13.	TAYLOR, et al. Retro-inverso proaspartic peptides retain bioactivity, are stable in vivo, and are blood-brain barrier permeable. <i>J Pharmacol Exp Ther.</i> 2000; 295(1):190-4.		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Indicate of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.86. The information is required to obtain or retain a benefit by the public which is so far (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: *Communications for Patents*, P.O. Box 1450, Alexandria, VA 22313-1450.

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